

Please cancel claims 36-47 and 50 without prejudice, as they are drawn to non-elected subject matter. Applicants reserve the right to pursue this subject matter in one or more continuation and/or divisional applications.

Please amend claims 1, 20-22, 24, 28-32 and 49 as follows:

--Claim 1. A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

20² b) mixing and emulsifying said first emulsion and a second aqueous phase in a mixer with an energy input to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

c) removing the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined size relative to energy input; and

d) filtering the multivesicular liposomal particle composition by cross-flow filtration, wherein all steps are carried out under aseptic conditions, and wherein all solutions are sterile filtered prior to use, and wherein the multivesicular liposomal particle composition is immediately suitable for administration into humans.--

--Claim 20. The process of claim 16, wherein the back pulse volume is from about 0.01% to about 5% of initial filtration volume.--

20³ --Claim 21. The process of claim 20, wherein the back pulsing volume is from about 0.1% to about 1.0% of initial filtration volume.--

--Claim 22. The process of claim 16, wherein the filtering is conducted at a retentate back pressure of from about 0 psi to about 10 psi.--

224 --Claim 24. The process of claim 23, wherein the potency adjustment is carried out by secondary filtration.--

--Claim 28. The process of claim 27, wherein a first solvent removal step is characterized by an inert gas flow rate that is less than that of a second step.--

225 --Claim 29. The process of claim 28, wherein the gas flow rate of the first solvent removal step is from about 20% to about 50% that of the second step.--

--Claim 30. The process of claim 27, wherein a first solvent removal step is characterized by an inert gas flow rate that is greater than that of the second step.--

--Claim 31. The process of claim 30, wherein the gas flow rate of the first solvent removal step is from about 120% to about 400% that of the second step.--

--Claim 32. The process of claim 28, further comprising a third solvent removal step, wherein the gas flow rate of the third solvent removal step is less than that of the second solvent removal step.--

--Claim 49. A process for preparing a multivesicular liposomal particle composition, the process comprising:

De a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

b) mixing and emulsifying said first emulsion and a second aqueous phase in a mixer with an energy input to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

c) removing the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined size relative to energy input; and

d) filtering the multivesicular liposomal particle composition by cross-flow filtration, wherein the resulting multivesicular liposomal particle composition is sterilized before filling, and wherein the multivesicular liposomal particle composition is immediately suitable for administration into humans.--

Please add the following new claims:

--Claim 54. A process for preparing a multivesicular liposomal particle composition, the process comprising:

207 a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

b) mixing and emulsifying said first emulsion and a second aqueous phase in a mixer with a power input to provide a second emulsion, said second emulsion comprising a continuous aqueous phase; and

c) removing the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined size relative to power input; wherein power = (linear flow rate through mixer) x (pressure drop across mixer).

Claim 55. The process of claim 54, wherein all steps are carried out under aseptic conditions, wherein all solutions are sterile filtered prior to use, and wherein the multivesicular liposomal particle composition is immediately suitable for administration into humans.

Claim 56. The process of claim 54, wherein the resulting multivesicular liposomal particle composition is sterilized before filling, and wherein the multivesicular liposomal particle composition is immediately suitable for administration into humans.

Claim 57. The process of claim 54, wherein the mixer is a static mixer.

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Claim 58. The process of claim 54, wherein the first emulsion and the second aqueous solution are passed through the mixer at a linear velocity of from about 100 cm/min to about 500 cm/min.

Claim 59. The process of claim 54, wherein the volume ratio of the first aqueous phase to the water-immiscible solvent phase is from about 0.33 to about 16.

Claim 60. The process of claim 54, wherein the volume ratio of the first emulsion to the second aqueous phase is from about 0.05 to about 0.5.

Claim 61. The process of claim 54, wherein the solvent removal comprises contacting the second emulsion with an inert gas flow.

Claim 62. The process of claim 54 further comprising filtering the multivesicular liposomal particle composition by cross-flow filtration. --
